

HALOBETASOL PROPIONATE- halobetasol propionate aerosol, foam Mayne Pharma

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HALOBETASOL PROPIONATE TOPICAL FOAM safely and effectively. See full prescribing information for HALOBETASOL PROPIONATE TOPICAL FOAM.

HALOBETASOL PROPIONATE topical foam

Initial U.S. Approval: 1990

RECENT MAJOR CHANGES

Indication and Usage (1)

05/2021

INDICATIONS AND USAGE

Halobetasol Propionate Topical Foam is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients twelve (12) years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Shake before use. (2)
- Apply Halobetasol Propionate Topical Foam as a thin uniform film to the affected skin twice daily for up to two weeks. Rub in gently. (2)
- Do not use more than 50 grams per week. (2)
- Discontinue Halobetasol Propionate Topical Foam when control is achieved. (2)
- If no improvement is seen within 2 weeks, reassess diagnosis. (2)
- Treatment beyond 2 consecutive weeks is not recommended. (2)
- Do not use with occlusive dressings unless directed by a physician. (2)
- Avoid use on the face, groin, or axillae. (2)
- Halobetasol Propionate Topical Foam is not for ophthalmic, oral, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Topical foam: 0.05% (0.5 mg/g). (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur, with the potential for glucocorticosteroid insufficiency during or after treatment. (5.1)
- Systemic effects following prolonged exposure of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. (5.1)
- Use of potent corticosteroids on large areas, for prolonged durations, under occlusive dressings, or on an altered skin barrier may increase systemic exposure. (5.1)
- Children may be more susceptible to systemic toxicity when treated with topical corticosteroids. (5.1, 8.4)
- Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation, and allergic contact dermatitis. Adverse reactions may be more likely to occur with occlusive use or more potent corticosteroids. (5.2)
- Topical corticosteroids may increase the risk of cataract and glaucoma formation. If visual symptoms occur, consider referral to an ophthalmologist for evaluation. (5.3)
- Initiate appropriate therapy if concomitant skin infections develop. (5.4)
- Flammable contents. Avoid heat, flame, or smoking during and immediately following application. (5.6)

ADVERSE REACTIONS

The most commonly reported adverse reactions ($\geq 1\%$) are application site pain and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Padagis at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 11/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Adverse Endocrine Effects

5.2 Local Adverse Reactions

5.3 Ophthalmic Adverse Reactions

5.4 Concomitant Skin Infections

5.5 Allergic Contact Dermatitis

5.6 Flammability

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

16.2 Storage

16.3 Handling

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Halobetasol Propionate Topical Foam is indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

Shake can prior to use and turn can completely upside down to dispense. Apply Halobetasol Propionate Topical Foam as a thin uniform film to the affected skin twice daily for up to two weeks. Rub in gently. Wash hands after applying the product.

Discontinue therapy when control is achieved. If no improvement is seen within two weeks, reassessment of the diagnosis may be necessary.

Treatment beyond two weeks is not recommended and the total dosage should not exceed 50 grams per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see *Warnings and Precautions (5.1)*]. Do not use with occlusive dressings unless directed by a physician.

Avoid use on the face, groin, or axillae.

Avoid contact with eyes. Wash hands after each application, unless it is for treatment of the hands.

Halobetasol propionate topical foam is for topical use only.

Halobetasol propionate topical foam is not for ophthalmic, oral, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Halobetasol Propionate Topical Foam is a white to off-white topical foam. Each gram of Halobetasol Propionate Topical Foam, 0.05% contains 0.5 mg of halobetasol propionate.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Adverse Endocrine Effects

Halobetasol Propionate Topical Foam is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic effects of topical corticosteroids may include reversible HPA axis suppression, with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment of the topical corticosteroid. The potential for hypothalamic-pituitary-adrenal (HPA) suppression with Halobetasol Propionate Topical Foam was evaluated in the following studies:

- In a study of 25 adult subjects with moderate to severe plaque psoriasis involving $\geq 15\%$ of their body surface area. Halobetasol Propionate Topical Foam produced laboratory evidence of HPA axis suppression when used twice daily for two weeks in 6 out of 25 (24%) adult subjects with plaque psoriasis. All subjects returned to

normal HPA axis function at follow-up at least 4 weeks after stopping the treatment [see *Clinical Pharmacology (12.2)*].

- In another clinical study, 24 subjects 12 to less than 18 years old with stable plaque psoriasis involving 10% or more of their body surface area applied Halobetasol Propionate Topical Foam to affected areas twice daily for two weeks. Of the 23 subjects evaluated for HPA axis suppression, laboratory evidence of adrenal suppression occurred in 6 subjects (26.1%), whom recovered upon retesting after at least 4 weeks of stopping the treatment [see *Clinical Pharmacology (12.2)*].

Because of the potential for systemic absorption, use of topical corticosteroids, including Halobetasol Propionate Topical Foam, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use over large surface areas, prolonged use, occlusive use, use on an altered skin barrier, concomitant use of multiple corticosteroid-containing products, liver failure, and young age. An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, attempt to gradually withdraw the drug, reduce the frequency of application, or substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids.

Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids due to their larger surface-to-body mass ratios [see *Use in Specific Populations (8.4)*].

5.2 Local Adverse Reactions

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including Halobetasol Propionate Topical Foam. Some local adverse reactions may be irreversible.

5.3 Ophthalmic Adverse Reactions

Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported in postmarketing experience with the use of topical corticosteroid products.

Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.4 Concomitant Skin Infections

Use an appropriate antimicrobial agent if a skin infection is present or develops. If a

favorable response does not occur promptly, discontinue use of Halobetasol Propionate Topical Foam until the infection has been adequately treated.

5.5 Allergic Contact Dermatitis

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Consider confirmation of a clinical diagnosis of allergic contact dermatitis by appropriate patch testing. Discontinue Halobetasol Propionate Topical Foam if allergic contact dermatitis is established.

5.6 Flammability

Halobetasol Propionate Topical Foam is flammable. Avoid fire, flame, or smoking during and immediately following application.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression and Other Adverse Endocrine Effects [see *Warnings and Precautions (5.1)*]
- Allergic Contact Dermatitis [see *Warnings and Precautions (5.5)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In randomized, multicenter, vehicle-controlled clinical trials, 351 adults with plaque psoriasis were treated with Halobetasol Propionate Topical Foam twice daily for up to two weeks (up to approximately 50 grams per week). Table 1 presents selected adverse reactions that occurred in at least 1% of subjects.

Table 1: Adverse Reactions Occurring in \geq 1% of Subjects through Week 2

	HBP Foam N=351	Vehicle Foam N=353
Adverse Reaction	%	%
Application site burning/stinging	12%	15%
Application site pain	1%	<1%
Headache	1%	<1%

Skin atrophy (n=1) and telangiectasia (n=2) were reported with Halobetasol Propionate Topical Foam, but not with vehicle foam.

6.2 Postmarketing Experience

Because the reactions are reported voluntarily from a population of uncertain size, it is

not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following local adverse reactions have been reported with topical corticosteroids: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, irritation, striae, and miliaria. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids, such as halobetasol propionate.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Halobetasol Propionate Topical Foam use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. In animal reproduction studies, increased malformations, including cleft palate and omphalocele, were observed after oral administration of halobetasol propionate during organogenesis to pregnant rats and rabbits. No comparisons of animal exposure with human exposure may be calculated due to minimal systemic exposure in humans after topical administration of Halobetasol Propionate Topical Foam [see *Clinical Pharmacology* (12.3)].

The background risk of major birth defects and miscarriage for the indicated population are unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

Halobetasol propionate has been shown to cause malformations in rats and rabbits when given orally during organogenesis at doses of 0.04 to 0.1 mg/kg/day in rats and 0.01 mg/kg/day in rabbits. Halobetasol propionate was embryotoxic in rabbits, but not in rats. Cleft palate was observed in both rats and rabbits. Omphalocele was seen in rats, but not in rabbits.

8.2 Lactation

Risk Summary

There are no data on the presence of halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after topical application to women who are breastfeeding.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Halobetasol Propionate Topical Foam and any potential adverse effects on the breastfed infant from Halobetasol Propionate Topical Foam or from the

underlying maternal condition.

Clinical Considerations

Advise breastfeeding women not to apply Halobetasol Propionate Topical Foam directly to the nipple and/or areola to avoid direct infant exposure.

8.4 Pediatric Use

Safety and effectiveness of Halobetasol Propionate Topical Foam in patients younger than 12 years of age have not been established; therefore, use in children younger than 12 years is not recommended.

The safety and effectiveness of Halobetasol Propionate Topical Foam for the treatment of stable plaque psoriasis in subjects 12 to less than 18 years of age is supported by evidence from adequate and well-controlled studies in adults and from one open-label safety study in 24 subjects aged 12 to less than 18 years. Subjects 12 to less than 18 years with stable plaque psoriasis covering a minimum of 10% of the total body surface area at baseline were treated twice daily for 2 weeks with Halobetasol Propionate Topical Foam. Hypothalamic-pituitary-adrenal (HPA) axis function (ACTH stimulation test) was evaluated in a subset of 23 subjects. After 2 weeks of treatment, 6 of 23 subjects (26.1%) experienced laboratory evidence of adrenal suppression (i.e., cortisol serum level of ≤ 18 $\mu\text{g/dL}$) that recovered upon retesting after at least 4 weeks of stopping the treatment [see *Clinical Pharmacology (12.2)*].

Because of higher skin surface area to body mass ratios, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children [see *Warnings and Precautions (5.1)*].

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema [see *Warnings and Precautions (5.1)*].

8.5 Geriatric Use

Clinical studies with Halobetasol Propionate Topical Foam included 131 patients aged 65 years and over. No overall differences in safety or effectiveness were observed between these patients and those younger than 65 years.

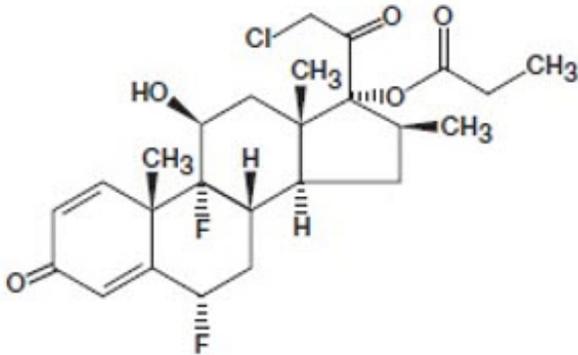
10 OVERDOSAGE

Topically applied Halobetasol Propionate Topical Foam can be absorbed in sufficient amounts to produce systemic effects [see *Warnings and Precautions (5.1)*].

11 DESCRIPTION

Halobetasol Propionate Topical Foam is a hydroethanolic aerosol foam that contains a

corticosteroid, halobetasol propionate. The chemical name of halobetasol propionate is 21-chloro-6 α , 9-difluoro-11 β , 17-dihydroxy-16 β -methylpregna-1, 4-diene-3,20-dione 17-propionate. Halobetasol propionate is a white to off-white crystalline powder with a molecular weight of 484.96 and a molecular formula of C₂₅H₃₁ClF₂O₅. It has the following structural formula:



It is practically insoluble in water and freely soluble in dichloromethane and in acetone. Each gram of Halobetasol Propionate Topical Foam contains 0.5 mg of halobetasol propionate in a white to off-white foam base consisting of alcohol (dehydrated), benzoic acid, cetostearyl alcohol, emulsifying wax, polyoxyl 20 cetostearyl ether, propylene glycol and purified water. Halobetasol Propionate Topical Foam is dispensed from an aluminum can pressurized with a hydrocarbon (isobutane and propane) propellant.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action in plaque psoriasis is unknown.

12.2 Pharmacodynamics

Vasoconstrictor Assay

A vasoconstrictor assay in healthy patients with Halobetasol Propionate Topical Foam, 0.05% indicated that the formulation is in the super-high range of potency as compared to other topical corticosteroids; however, similar blanching scores do not necessarily imply therapeutic equivalence.

Hypothalamic-pituitary-adrenal (HPA) axis suppression

The potential for hypothalamic-pituitary-adrenal (HPA) suppression was evaluated in the following two studies. In both studies, the criteria for HPA-axis suppression was a serum cortisol level of less than or equal to 18 micrograms per deciliter 30 minutes after stimulation with cosyntropin (adrenocorticotrophic hormone, ACTH). In the first study, Halobetasol Propionate Topical Foam was applied to 25 adult subjects with moderate to severe plaque psoriasis involving a mean body surface area of 18.4%. A mean dose of 3.7 g of Halobetasol Propionate Topical Foam was applied twice daily for two weeks and produced laboratory evidence of HPA axis suppression in 6 of 25 (24%) subjects. All subjects returned to normal HPA axis function at follow-up at least 4 weeks after

stopping the treatment.

In the second study, Halobetasol Propionate Topical Foam was applied to 24 subjects 12 to less than 18 years of age with stable plaque psoriasis with a mean percent BSA of 15.1% (range of 11% to 23%). The mean dose of Halobetasol Propionate Topical Foam used was 3.1 grams, which was applied twice daily for two weeks. In the study, 24 subjects completed the study, and 23 subjects had evaluable ACTH stimulation tests. HPA axis suppression was observed in 6 of the 23 subjects (26.1%), and all subjects returned to normal HPA axis function at follow-up at least 4 weeks after stopping the treatment.

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

In the HPA-axis and pharmacokinetic study, as described above in *Clinical Pharmacology* (12.2), pharmacokinetics was evaluated in a subgroup of 23 adult subjects with moderate to severe plaque psoriasis following twice daily treatment for 14 days. Plasma concentration of halobetasol propionate (HBP) was measurable in all subjects and steady state was achieved by Day 14. The mean (\pm standard deviation) C_{\max} concentration for HBP on Day 14 was 199.7 ± 217.3 pg/mL, with the corresponding median T_{\max} value of 1 hour (range 0 - 12 hours); mean area under the halobetasol propionate concentration versus time curve over the dosing interval (AUC_t) was 1434.9 ± 1310.6 pg•h/mL.

In the HPA axis study in subjects 12 to less than 18 years [see *Clinical Pharmacology* (12.2)], trough plasma concentrations of HBP were measured on Day 8 and Day 15 in 23 subjects following twice daily treatment for 14 days. On Day 8, nine (9) of the 23 evaluable subjects had morning trough concentrations of halobetasol propionate in plasma that were above the quantifiable limit (≥ 20.0 pg/mL); mean halobetasol concentration was 154.6 ± 308.67 pg/mL. Similarly, on Day 15, nine (9) of the 23 evaluable subjects had morning trough concentrations of halobetasol propionate above the quantifiable limit; mean halobetasol concentration was 59.9 ± 90.15 pg/mL. Of the 9 subjects with quantifiable plasma concentrations at Day 15, seven (7) also had quantifiable plasma concentrations at Day 8.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate.

In a 90-day repeat-dose toxicity study in rats, topical administration of Halobetasol Propionate Topical Foam at dose concentrations from 0.005% to 0.05% or from 0.011 to 0.11 mg/kg/day of halobetasol propionate resulted in a toxicity profile consistent with long-term exposure to corticosteroids including adrenal atrophy, histopathological changes in several organ systems indicative of severe immune suppression, and opportunistic fungal and bacterial infections. A no observable adverse effect level could

not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis.

Halobetasol propionate was not found to be genotoxic in the Ames/Salmonella assay, in the Chinese hamster CHO/HGPRT assay, in the mouse micronucleus test, in the sister chromatid exchange test in somatic cells of the Chinese hamster, or in the chromosome aberration test in somatic cells of Chinese hamsters. Positive mutagenicity effects were observed in two genotoxicity assays: Chinese hamster nuclear anomaly test and mouse lymphoma gene mutation assay in vitro.

Studies in the rat following oral administration at dose levels up to 0.05 mg/kg/day indicated no impairment of fertility or general reproductive performance.

14 CLINICAL STUDIES

Halobetasol Propionate Topical Foam was evaluated for the treatment of moderate to severe plaque psoriasis in two multicenter, randomized, double-blind, vehicle-controlled studies (Study 1 [NCT02368210] and Study 2 [NCT02742441]).

These studies were conducted in 560 subjects 18 years of age and older with plaque psoriasis involving between 2% and 12% body surface area. Baseline disease severity was determined using a static, five-level Investigator's Global Assessment (IGA) scale, on which a subject scored either moderate or severe. Overall, approximately 60% of subjects were male and approximately 90% were Caucasian.

Subjects applied Halobetasol Propionate Topical Foam or vehicle to all affected areas twice daily for up to 14 consecutive days.

The primary measure of efficacy was Overall Treatment Success, defined as the proportion of subjects who were cleared or almost cleared with at least a two-grade improvement from baseline at Week 2 (end of treatment) based on the IGA. The studies also evaluated treatment success for the individual signs of psoriasis (plaque elevation, scaling, and erythema) at the end of treatment. Table 2 presents these results.

Table 2: Efficacy Results at Week 2 in Subjects with Plaque Psoriasis

	Study 1		Study 2	
	Halobetasol Propionate Topical Foam N=75	Vehicle Foam N=76	Halobetasol Propionate Topical Foam N=205	Vehicle Foam N=204
Overall Treatment Success*	19 (25%)	3 (4%)	63 (31%)	15 (7%)
Plaque Elevation†	20/75 (27%)	3/76 (4%)	71/202 (35%)	20/203 (10%)
Scaling†	21/75 (28%)	4/76 (5%)	68/201 (34%)	20/204 (10%)
			50/205	

Erythema†	16/75 (21%)	2/76 (3%)	59/205 (29%)	17/204 (8%)
-----------	-------------	-----------	-----------------	-------------

* Subjects whose condition was cleared or almost cleared of all signs of psoriasis and with at least a two-grade improvement from baseline based on the IGA.

† Subjects who were cleared or almost cleared of the designated clinical sign with at least a two-grade improvement from baseline. Individual signs were rated by severity using a five-point scale ranging from 0 (clear) to 4 (severe). Subjects with baseline value of 0 or 1 were excluded.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Halobetasol Propionate Topical Foam, 0.05% is a white to off-white foam.

It is supplied in aluminum cans of:

50 grams (NDC 68308-769-50)

16.2 Storage

Store at 20°-25°C (68°-77°F); excursions permitted to 15°C and 30°C (59°F to 86°F). Contents under pressure.

Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C). Do not freeze.

16.3 Handling

Halobetasol Propionate Topical Foam is flammable; avoid heat, flame, or smoking when using this product.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all administration instructions or all possible adverse or unintended effects.

Inform patients of the following:

Important Administration Instructions:

- Total dosage should not exceed 50 grams (one can) per week [see *Dosage and Administration (2)*].
- Advise patients to avoid use on the face, groin, or axillae. Avoid contact with eyes [see *Dosage and Administration (2)*].
- Inform patients that topical corticosteroids may cause HPA axis suppression and local adverse reactions [see *Warnings and Precautions (5.1)*].
- Breastfeeding women should not apply Halobetasol Propionate Topical Foam directly to the nipple and/or areola to avoid direct exposure to the infant [see *Use in Specific*

Populations (8.2)].

- This product is flammable; avoid heat, flame, or smoking during and immediately following application of this product.

Rx Only

Distributed by:

Mayne Pharma

Raleigh, NC 27609

Rev 05/2023

Patient Information

PATIENT INFORMATION Halobetasol Propionate (hal-oh-BAY-ta-sol PRO-pee-oh-nate) Topical Foam, 0.05%
Important: Halobetasol Propionate Topical Foam is for use on the skin only. Do not apply Halobetasol Propionate Topical Foam near or in your eyes, mouth, or vagina.
What is Halobetasol Propionate Topical Foam? Halobetasol Propionate Topical Foam is a prescription corticosteroid medicine used on the skin to treat plaque psoriasis in people 12 years of age and older. It is not known if Halobetasol Propionate Topical Foam is safe and effective in children under 12 years of age.
Before using Halobetasol Propionate Topical Foam, tell your healthcare provider about all of your medical conditions, including if you: <ul style="list-style-type: none">• have had irritation or other skin reaction to a steroid medicine in the past.• have a skin infection. You may need medicine to treat the skin infection before using Halobetasol Propionate Topical Foam.• have diabetes.• have adrenal gland problems.• have liver problems.• plan to have surgery.• are pregnant or plan to become pregnant. It is not known if Halobetasol Propionate Topical Foam will harm your unborn baby.• are breastfeeding or plan to breastfeed. It is not known if halobetasol propionate passes into your breast milk. If you use Halobetasol Propionate Topical Foam and breastfeed, do not apply Halobetasol Propionate Topical Foam to your nipple or areola to avoid getting Halobetasol Propionate Topical Foam into your baby's mouth.
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take other corticosteroid medicines by mouth, or injection, or use other products on your skin that contain corticosteroid.
How should I use Halobetasol Propionate Topical Foam? <ul style="list-style-type: none">• Use Halobetasol Propionate Topical Foam exactly as your healthcare provider tells you to use it.• Apply a thin layer of Halobetasol Propionate Topical Foam to the affected skin areas 2

times each day.

- You should not use more than 50 grams of Halobetasol Propionate Topical Foam in 1 week.
- Avoid using Halobetasol Propionate Topical Foam on your face, underarms (armpits), or groin areas.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.
- Talk to your healthcare provider if your skin does not improve after 2 weeks of treatment with Halobetasol Propionate Topical Foam.
- Do not use Halobetasol Propionate Topical Foam longer than 2 continuous weeks unless advised to do so by your prescriber.
- Wash your hands after using Halobetasol Propionate Topical Foam unless you are using the medicine to treat your hands.

What should I avoid while using Halobetasol Propionate Topical Foam?

Halobetasol Propionate Topical Foam is flammable. Avoid heat, flame, or smoking during and right after applying Halobetasol Propionate Topical Foam to your skin.

What are the possible side effects of Halobetasol Propionate Topical Foam?

Halobetasol Propionate Topical Foam may cause serious side effects, including:

- **Halobetasol Propionate Topical Foam can pass through your skin.** Too much Halobetasol Propionate Topical Foam passing through your skin can cause adrenal glands to stop working.
- **Cushing's syndrome**, a condition that happens when your body is exposed to too much of the hormone cortisol.
- **High blood sugar** (hyperglycemia).
- **Vision problems.** Halobetasol Propionate Topical Foam may increase your chance of developing cataract(s) and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with Halobetasol Propionate Topical Foam.
- **Skin reactions at the treated skin site.** Tell your healthcare provider if you get any skin reactions or skin infections.
- **Effects on growth and weight in children.**

Your healthcare provider may do certain blood tests to check for side effects.

The most common side effect of Halobetasol Propionate Topical Foam is mild to moderate pain at the treated site.

These are not all of the possible side effects of Halobetasol Propionate Topical Foam. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Halobetasol Propionate Topical Foam?

- Store Halobetasol Propionate Topical Foam at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not puncture or burn Halobetasol Propionate Topical Foam can.
- Do not store Halobetasol Propionate Topical Foam next to heat or store at temperatures above 120°F (49°C).
- Do not freeze Halobetasol Propionate Topical Foam.

Keep Halobetasol Propionate Topical Foam and all medicines out of the reach of children.

General information about the safe and effective use of Halobetasol

Propionate Topical Foam.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Halobetasol Propionate Topical Foam for a condition for which it was not prescribed. Do not give Halobetasol Propionate Topical Foam to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Halobetasol Propionate Topical Foam that is written for health professionals.

What are the ingredients in halobetasol propionate topical foam?

Active ingredient: halobetasol propionate

Inactive ingredients: alcohol (dehydrated), benzoic acid, cetostearyl alcohol, emulsifying wax, polyoxyl 20 cetostearyl ether, propylene glycol, and purified water. Halobetasol Propionate Topical Foam is dispensed from an aluminum can pressurized with a hydrocarbon propellant containing isobutane and propane.

Distributed by:

Mayne Pharma

Raleigh, NC 27609

For more information, call 1-866-634-9120

This Patient Information has been approved by the U.S. Food and Drug Administration

Revised: 05/2023

Instructions for Use

INSTRUCTIONS FOR USE

Halobetasol Propionate (hal-oh-BAY-ta-sol PRO-pee-oh-nate) Topical Foam, 0.05%

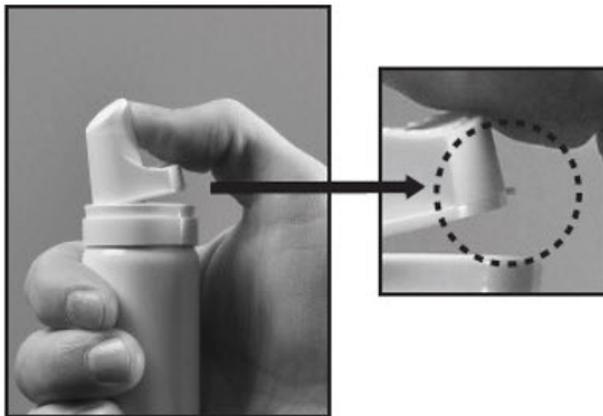
Read the Patient Information and Instructions for Use before you use Halobetasol Propionate Topical Foam.

Important information: Halobetasol Propionate Topical Foam is for skin use only. Do not get Halobetasol Propionate Topical Foam in your mouth, eyes, or vagina.

Parts of the Halobetasol Propionate Topical Foam can:



Step 1: Before applying Halobetasol Propionate Topical Foam for the first time, remove cap and break the small tab at the base of the actuator by gently pushing the actuator away from the tab as shown. Do not break the hinge on the actuator.



Step 2: Shake the can well before use.



Step 3: Turn the can completely upside down.



Step 4: Press down on the actuator to dispense a small amount of the foam into the palm of your hand.



Step 5: Apply a thin layer of Halobetasol Propionate Topical Foam to the affected skin area. Gently rub Halobetasol Propionate Topical Foam into the affected skin until the foam disappears. Repeat Steps 4 and 5 to all the affected areas as prescribed by your healthcare provider.



Step 6: After applying Halobetasol Propionate Topical Foam, put the cap back on the can.

Step 7: Wash your hands after applying Halobetasol Propionate Topical Foam unless you are using the medicine to treat your hands.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Distributed by:

Mayne Pharma
Raleigh, NC 27609

Rev 05/2023

PRINCIPAL DISPLAY PANEL - 50 g Canister Carton

NDC 68308-769-50

Halobetasol
Propionate
Topical Foam, 0.05%

For topical use only.

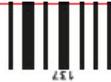
Not for ophthalmic, oral,
or intravaginal use.

Keep Out of Reach
of Children.

Rx ONLY

Net Wt. 50 g

mayne pharma



30206462
137
ly

NDC 68308-769-50
Halobetasol Propionate
Topical Foam, 0.05%
Net Wt. 50 g

A-0112
1 2 3 4 5
6 7 8 9 10

NDC 68308-769-50

 **Halobetasol Propionate**
Topical Foam, 0.05%

NDC 68308-769-50

 **Halobetasol Propionate**
Topical Foam, 0.05%

Rx ONLY

IMPORTANT: Shake well before each application and turn can completely upside down to dispense.

Usual Dosage: Apply twice daily to affected skin areas or as directed by physician. Rub in gently. Do not use more than 50 grams per week (one can). See package insert for full Prescribing Information, Patient Information, and Instructions for Use.

Each gram contains:
Active: halobetasol propionate 0.5mg.
Inactive: alcohol (dehydrated), benzoic acid, cetostearyl alcohol, emulsifying wax, polyoxyl 20 cetostearyl ether, propylene glycol and purified water. Pressurized with hydrocarbon (isobutane and propane) propellant.

For topical use only.

Not for ophthalmic, oral, or intravaginal use.

Keep Out of Reach of Children.

Rx ONLY

Warning: Flammable. Avoid fire, flame, or smoking during and immediately following application.

Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from freezing.



3 68308 76950 1

See lot number and expiration date on the bottom flap of this carton.

Net Wt. 50 g



For topical use only.

Not for ophthalmic, oral, or intravaginal use.

Keep Out of Reach of Children.

Distributed by:
Mayne Pharma
Raleigh, NC 27609

Internal Rev. 05/2023
Product of India

Net Wt. 50 g



36P8X LE C1



HALOBETASOL PROPIONATE

halobetasol propionate aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68308-769
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Halobetasol propionate (UNII: 91A0K1TY3Z) (Halobetasol - UNII:9P6159HM7T)	Halobetasol propionate	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
POLAWAX POLYSORBATE (UNII: Q504PL8E0V)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWJY)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Water (UNII: 059QF0KO0R)	
Benzoic Acid (UNII: 8SKN0B0MIM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68308-769-50	1 in 1 CARTON	12/01/2023	
1		50 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215266	11/27/2023	

Labeler - Mayne Pharma (867220261)

Registrant - Padagis Israel Pharmaceuticals Ltd. (600093611)

Establishment

Name	Address	ID/FEI	Business Operations
Padagis Israel Pharmaceuticals Ltd.		600093611	MANUFACTURE(68308-769)

Revised: 11/2023

Mayne Pharma